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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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097058,589 04/10/98 KIMBER

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EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

12/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

<p align="center"><b>Office Action Summary</b></p>	Application No. 09/058,589	Applicant(s) KIMBER ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2000.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 11 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-10, 12-14 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Receipt of the amendments and remarks submitted September 18, 2000 is acknowledged.

1. This application contains claims 2-4 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### *Claims Rejection 35 U.S.C. – 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1, 5-10,12-14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Nuijens et al and Enk et al.(Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998), Database WPI AN 95-340208 (IDS October 2, 1998) and Penco et al. (of record).

4. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

5. Teng et al. do not teach using this method to inhibiting the inflammatory activity of IL-1beta in inflammatory dermal disorders herein or the employment of biological analog or fragments of lactoferrin.

6. However, Nuijens et al. teach that lactoferrin reduces the production of IL-1beta and TNF alpha and inhibit proliferation. See, particularly, page 287, third paragraph. Enk et al. teach that

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both IL-1beta and TNFalpha are responsible for promoting inflammatory activity, including the allergen-induced inflammatory activity. See, particularly, the abstract. Penco et al. further teach that lactoferrin inhibits the activity of IL-1beta. See, the abstract. Database WPI AN 95-340208 disclose that lactoferrin analog and fragments are known to be similarly useful as lactoferrin in treating dermal disorder. See the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta or to employ the lactoferrin active biological analog or active fragments in Teng's method.

A person of ordinary skill in the art would have been motivated to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta or to employ the lactoferrin biological analog or active fragments in Teng's method because lactoferrin is known for reducing the production of IL-1beta and TNF alpha and inhibiting the activity of IL-1beta and the lactoferrin active biological analog or active fragments are known to be similarly useful for treatment of dermal disorder.

7. Claims 5-10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. in view of Nuijens et al. Database WPI AN 95-340208 (IDS October 2, 1998) and Enk et al. (Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998).

8. Teng et al teach a method of treating dermal inflammatory disorder of humans comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

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Teng et al. do not teach specifically to use this method to treat an allergen-induced dermal inflammatory disorder or the employment of biological analog or fragments of lactoferrin.

However, Nuijens et al. teach that lactoferrin reduces the productions of IL-1beta and TNF alpha and inhibit proliferation. See, particularly, page 287, third paragraph. Enk et al. teach that both IL-1beta and TNFalpha are responsible for promoting inflammatory activity, including the allergen-induced inflammatory activity. See, particularly, the abstract. Database WPI AN 95-340208 disclose that lactoferrin analog and fragments are known to be similarly useful as lactoferrin in treating dermal disorders including allergen-induced inflammatory disorders. See the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use the method of Teng et al. for treating an allergen-induced dermal inflammatory disorder or to employ the lactoferrin biological analog or active fragments in Teng's method.

A person of ordinary skill in the art would have been motivated to use the method of Teng et al. for treating an allergen-induced dermal inflammatory disorder or to employ the lactoferrin biological analog or active fragments in Teng's method because lactoferrin is known for reducing the production of IL-1beta and TNFalpha and inhibiting the activity of IL-1beta and the lactoferrin active biological analog or active fragments are known to be similarly useful for treatment of dermal disorder including the allergen-induced dermal inflammatory disorder.

9. Applicants' remarks submitted September 18, 2000 have been fully considered, but are not persuasive for reasons discussed below.

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10. Regarding applicants' remarks that Teng et al. do not teach a method of treating dermal inflammatory disorder, note that Teng particularly teach lactoferrin is known to be useful for treating "skin infection." The inflammation is well known in the art to be a symptom of skin infections. Further, Teng et al. teach that deficiency of lactoferrin is an etiological condition causing the symptom of inflammation. A method for correcting etiological condition is deemed to be useful for releasing the symptom. Issues of symptomatology should not be confused with issue of etiology.

11. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. Applicants' attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." The ultimate utility for lactoferrin, i.e., anti-inflammation, is known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims, including the newly added claim 20, are properly rejected under 35 U.S.C. 103.

Nothing unobvious is seen in the claimed invention.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

AU 1617

November 28, 2000

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200